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EP 0860701 A1
WO 2000/062060 A2
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(54) Abstract Title
Test strips for determining analytes in a fluid

(57) Typically a dip and read device is in the form of a test card 10 having colorimetric test strips 26 for indicating the presence of e.g. drugs in a urine sample. The card 10 is characterised by having a reagent test pad(s) 36 which indicate the presence of any adulterants which may have been added to the test sample or whether the sample has been diluted.

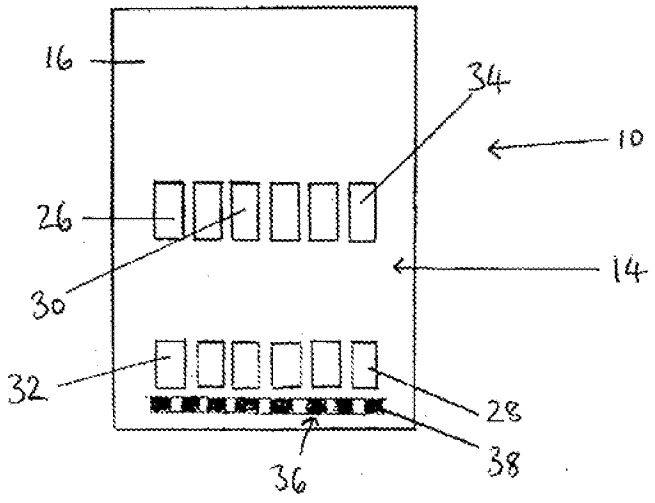

Fig 1

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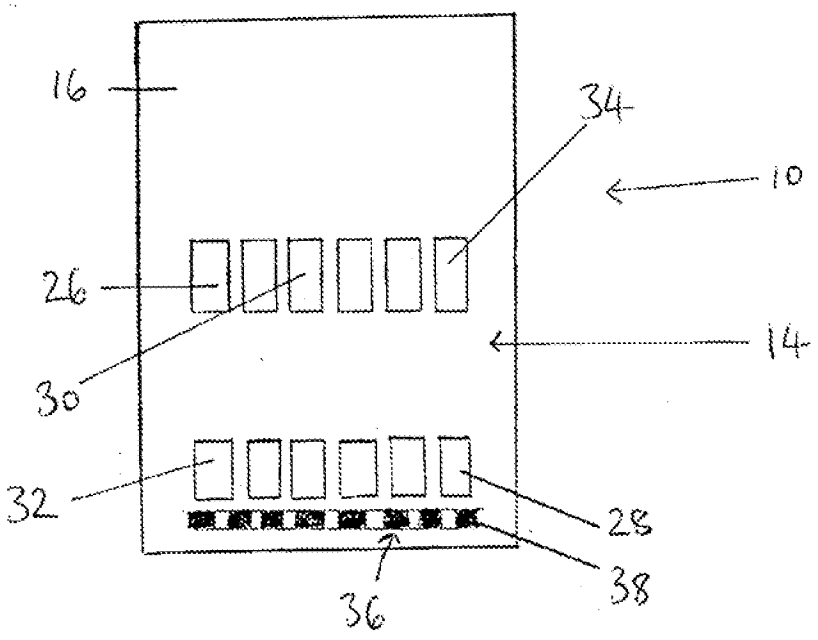
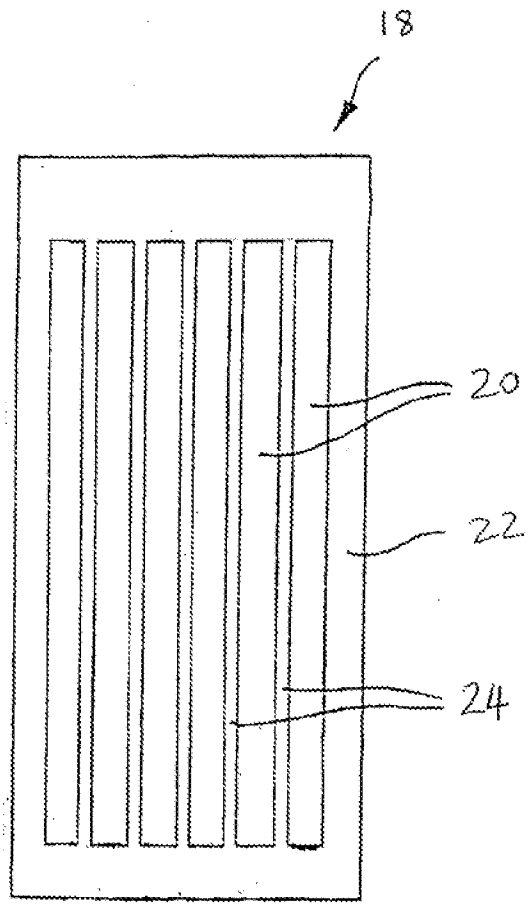


Fig 1

Fig 2



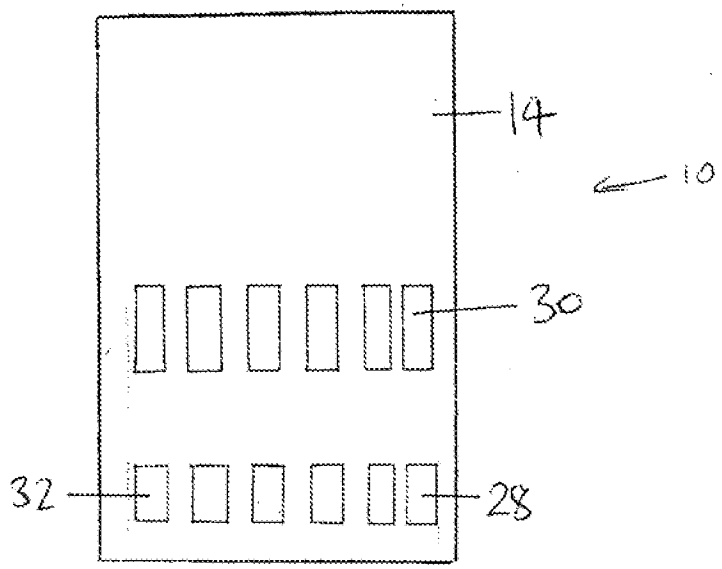
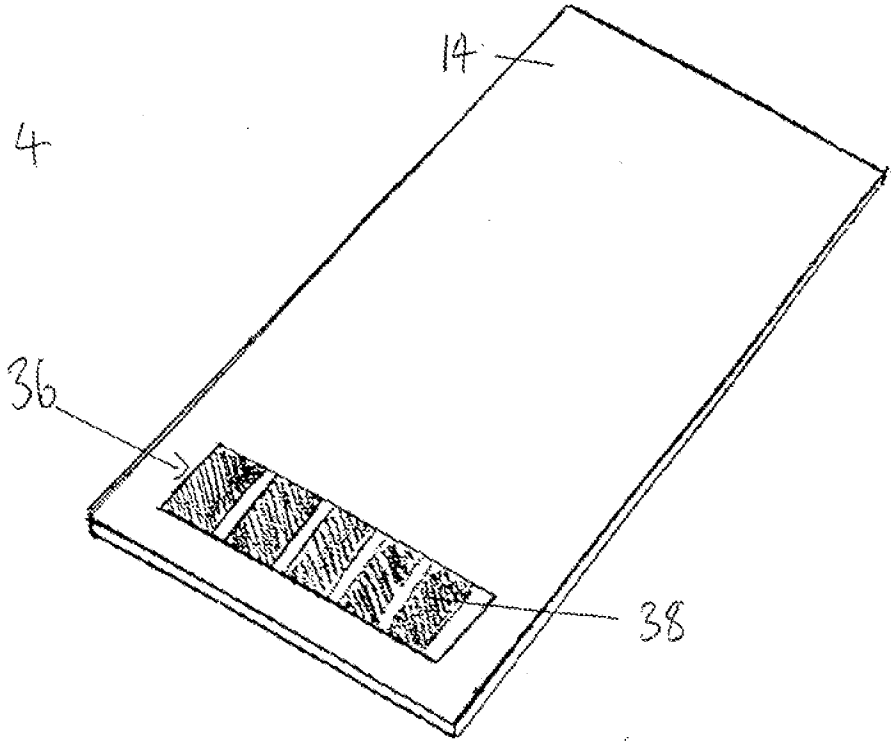


FIG 3

FIG 4



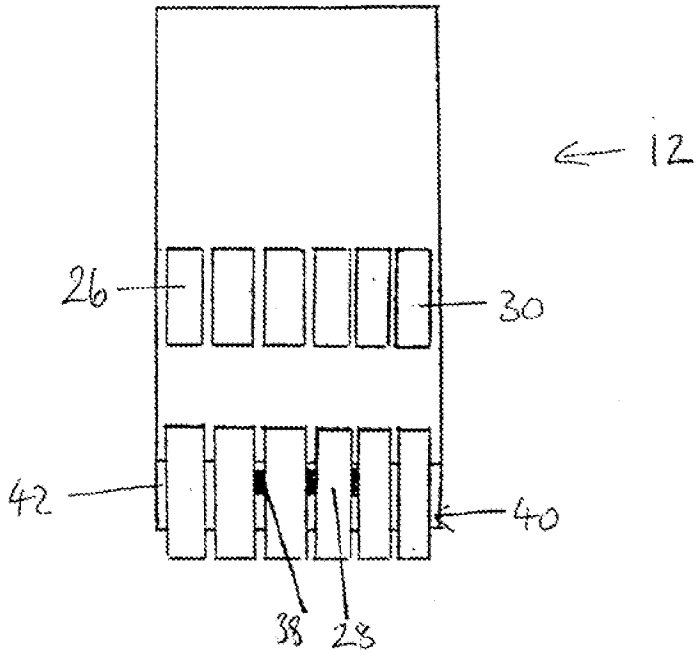


Fig 5

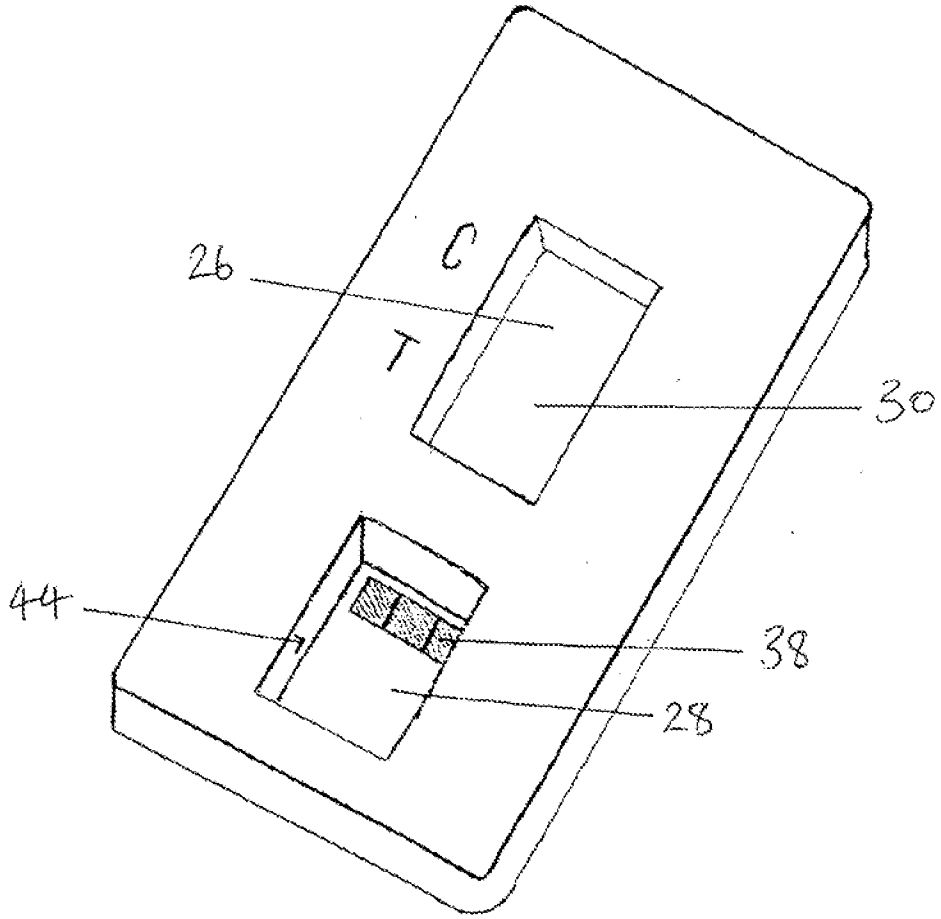


FIG 6

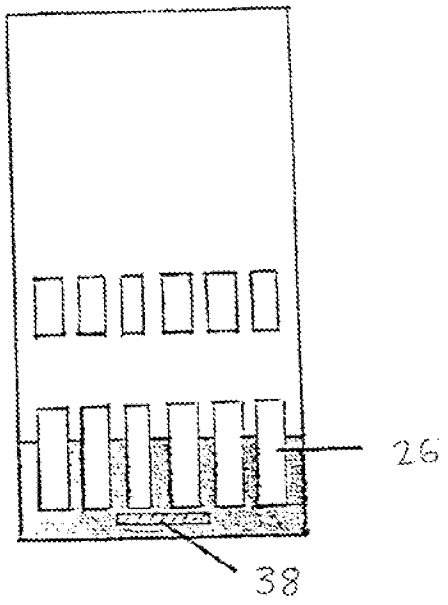


FIG 7A

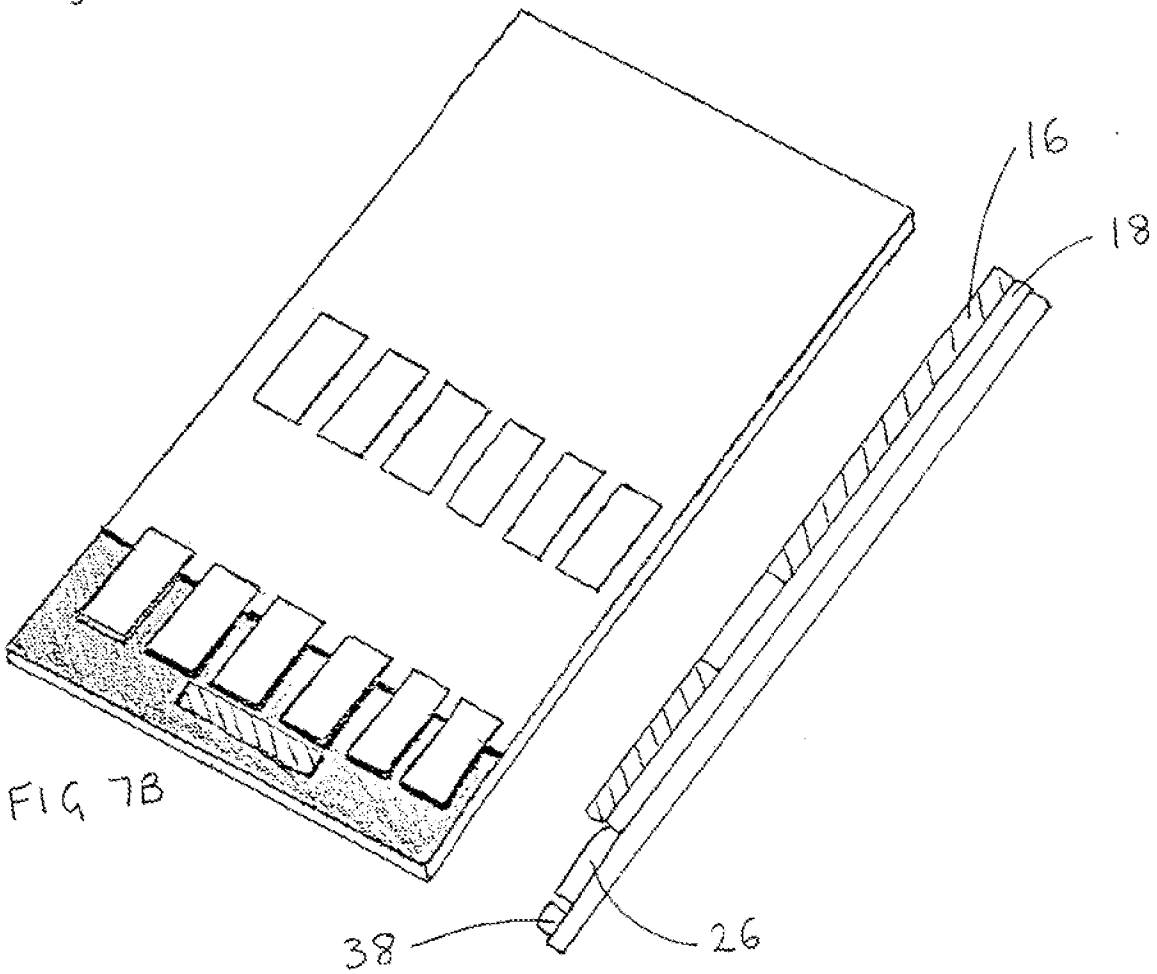
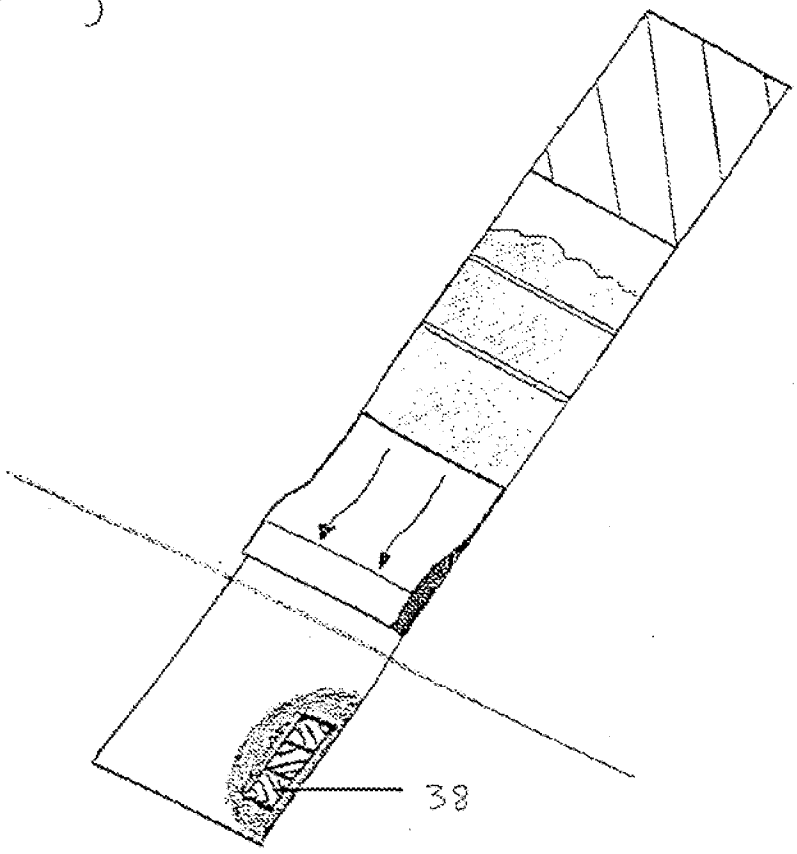


FIG 7B

FIG 7C

FIG 8



Testing Apparatus

This invention relates to testing apparatus for testing fluid mediums. A particular application of the invention is in testing urine samples for the presence of drugs.

Most drug screening uses lateral flow immunoassay test technology in which a sample of fluid to be tested passes along a lateral flow membrane and reacts with chemicals, such as antibodies, to test for the presence of a drug or other substance in the sample. The membrane is usually provided on a plastics strip and one or more strips may be mounted on or within a housing to form a testing apparatus. In use, the testing apparatus may be dipped into the sample to be tested or a small amount of the sample to be tested may be dropped onto the testing apparatus using a pipette.

As detection technology has advanced, substances have been developed which can be ingested or added to urine or other samples in order to interfere with the tests. In the case of drug tests for example, this makes it possible for a person who is taking the drugs being tested for to give a negative test result.

The above problem is particularly common in relation to the testing of urine samples for the presence of drugs. The adulteration of tests is possible because urine samples are given in private, thereby presenting an opportunity for a donor to add substances to the urine sample.

It is known to test urine samples for the presence of adulterating substances. Conventionally such adulteration tests are carried out separately to the drug tests themselves. This is time consuming and the samples need to be split between the tests. This also allows a further opportunity to adulterate the drug test sample whilst leaving the adulteration test sample clean.

According to the invention there is provided testing apparatus for testing a fluid medium, the apparatus including a test device for providing an

indication as to the presence of a selected substance within the medium and adulteration testing means for testing for adulteration of the sample which may affect the indication provided by the test device.

The adulteration may take the form of the addition of one more substances to the sample, the dilution of the sample or the substitution of the sample with an alternative substance.

Preferably the testing apparatus includes a single article incorporating the test device and the adulteration testing means.

The test device may include a lateral flow membrane and may be in the form of a test strip. The test device may include a sample receiving portion which may be provided at or towards an end of the test device. The test device may further include a reaction portion which provides the indication as to the presence of the selected substance within the medium. The reaction portion may be spaced from the sample receiving portion.

The adulteration testing means may be provided at or near the sample receiving portion of the test device.

The testing apparatus preferably includes a housing. The test device may be mounted on or preferably within the housing. The housing may be provided with an opening adjacent to the sample receiving portion of the test device. The housing may include an opening adjacent to the reaction portion of the test device. The housing may include two generally planar panel members between which the test device is sandwiched.

The testing apparatus may include a plurality of test devices which may each include a lateral flow membrane and which may each be in the form of a test strip. Preferably each test device includes a sample receiving portion, the respective sample receiving portions being aligned towards an end of the housing. The adulteration testing means may be mounted on or within the

housing near to the sample receiving portions of the test devices. The housing may include a plurality of discrete openings adjacent to the respective sample receiving portions of the test devices. The housing may further include a plurality of discrete openings adjacent to the reaction portions of the test devices.

The adulteration testing means may include means for testing for a plurality of different modes of adulteration. The adulteration testing means may include one or more pads of material each impregnated with a chemical reagent. The adulteration testing means may include a plastics strip member on which a plurality of pads of material are mounted, each pad being impregnated with a respectively different chemical reagent.

The fluid medium to be tested may be a urine sample. The selected substance may be a drug.

The adulteration testing means may include means for testing for dilution of the fluid medium, in particular for dilution of a urine sample. The adulteration testing means may include means for testing the specific gravity of the sample or for testing the levels of creatanine within the sample.

The adulteration testing means may include means for testing the pH of the sample.

The adulteration testing means may include means for testing for the presence of glutaraldehyde within the fluid medium.

The adulteration testing means may include means for testing for the presence of pyridinium chlorochromate within the fluid medium.

The adulteration testing means may include means for testing for the presence of nitrates within the fluid medium.

Embodiments of the invention will now be described for the purpose of illustration only with reference to the accompanying drawings in which:

Fig. 1 illustrates schematically testing apparatus according to the present invention;

Fig. 2 illustrates schematically a grid member of the testing apparatus of Fig. 1;

Fig. 3 illustrates schematically the front of testing apparatus according to a second embodiment of the present invention;

Fig. 4 shows a perspective view of the back of the testing apparatus of Fig. 3;

Fig. 5 illustrates schematically testing apparatus according to a third embodiment of the present invention;

Fig. 6 is a schematic perspective view of testing apparatus according to a fourth embodiment of the present invention;

Figs. 7A, 7B and 7C are schematic plan, perspective and side sectional views respectively of testing apparatus according to a fifth embodiment of the invention; and

Fig. 8 is a perspective view of testing apparatus according to a sixth embodiment of the invention.

Referring to Figs. 1 and 2 there is illustrated testing apparatus in the form of a dip card 10. The dip card 10 is suitable for testing for substances in fluid samples, for example drugs in urine samples.

The dip card 10 includes a housing 14 made up of front and rear panels, only the front panel 16 being visible in Fig. 1. The dip card 10 also includes a grid member 18 (see Fig. 2) sandwiched between the front and rear panels.

Referring to Fig. 2, the grid member 18 includes a plurality of elongate tracks 20 defined between elongate side members 22 and separator members 24.

The tracks 20 are sized to accommodate test devices in the form of test strips 26. The test strips 26 of the example shown in the figures are for testing for the presence of drugs in urine samples. Such drugs may include opiates, cannabis, cocaine and amphetamines amongst others. The test strips 26 consist of prepared enzyme immuno-chromatography strips manufactured from glass fibre designed individually to portray a positive or negative result of a drug in a urine sample at a prescribed limit. Each strip tests for a different drug.

Referring to Fig. 1, each test strip 26 includes a sample receiving portion 28 and a reaction portion 30. In use, the sample receiving portion 28 is brought into contact with urine, which then flows along the test strip by capillary action to the reaction portion 30, where a negative or positive result is displayed.

The test strips 26 are mounted in the grid member 18, which is sandwiched between the front and rear panels of the housing 14 of the dip card 10. The test strips 26 are located such that their sample receiving portions 28 are towards the bottom of the dip card 10 and their reaction portions 30 in a central region of the card.

As can be seen in Fig. 1, the front panel 16 of the housing 14 is provided with openings 32, a respective opening 32 being aligned with the sample receiving portion 28 of each test strip 26. The front panel is also provided with windows 34 through which the reaction portions 30 of the test strips 26 may be viewed. A respective window 34 is aligned with the reaction portion 30 of each test strip 26.

The dip card 10 further includes adulteration testing means in the form of an adulteration panel 36 attached to a front surface of the front panel 16. The adulteration panel includes an elongate plastics strip to which are attached eight discrete pads 38 of material, each being impregnated with a respectively different chemical, to test for different modes of adulteration.

Adulteration may take the form of:

1) Addition of substances to the sample. The substances may interfere with the working of the test or break down the substance being tested for.

2) Dilution of the sample. Drug tests are designed to work above a "cut-off level". For a urine sample to be positive, the quantity of drug present would have to be above the cut-off level. The level is deliberately set to be quite generous, in order that a person who has been accidentally exposed to the drug in small quantities will not fail a test. If the donor dilutes their urine sample, it is therefore possible that the level of drug will be diluted below the cut-off level even if the donor has taken the drugs in question. Dilution can be accomplished by adding water to the sample or by drinking copious amounts of water or taking a diuretic before the test.

3) Substitution. Other liquids which have the same colour as urine, for example grape juice, may be offered by the donor instead of urine.

The various ways in which the sample may have been adulterated can be tested for as follows:

1. <u>Addition of substances</u>

(i) Nitrates are one of the few classes of chemicals that break down cannabis metabolite and can cause a urine test to appear negative. An adulteration test may be provided to check whether nitrates have been added to the sample.

(ii) Glutaraldehyde interferes with laboratory based immunoassays and may be tested for.

(iii) Pyridinium Chlorochromate. Like nitrates, pyridinium

chlorochromate affects cannabis metabolite and may cause a false negative test on cannabis drug screening.

(iiii) Substances having a low or high pH may interfere with a drug test. Bleach, citric acid or ascorbic acid are acidic (i.e. they have a low pH) and detergents and caustic soda are alkaline (they have a high pH). The addition of such substances to urine may affect the test and this can be detected with a simple pH test.

2. Dilution

(i) The urine sample can be tested for specific gravity. If the specific gravity falls outside the normal range, the sample may be too dilute to be tested.

(ii) The creatanine level in the sample can be tested. Creatanine is a substance that is produced from the breakdown of muscle in the body. It is produced at an approximately constant rate and therefore if the amount in a sample falls outside the normal range, the sample is likely to have been diluted.

3. Substitution

The substances that are commonly substituted for urine include grape juice, which can be detected by a pH test. Other physical attributes may also be tested for.

In Fig. 1, each of the discrete pads 38 is impregnated with a different one of the above test substances. The substances may produce a positive result by, for example, a colour change. The pH test may be litmus paper or a universal indicator, from which the pH may be read in the normal way.

In use, the bottom of the dip card 10 is immersed in a urine sample so

that the sample receiving portions 28 of the strips 26, and therefore also the pads 38, are immersed. The dip card 10 is removed from the sample after an appropriate time period to avoid saturation and the fluid flows via the lateral flow membranes to the reaction portions 30 of the strips 26. The results of the drug tests can then be viewed through the windows 34 at the same time as the results of the adulteration tests on the pads 38. In this process, there is no need to separately test a sample for adulteration before or after testing it for drugs as was previously the case.

It is important that the dyes in the adulteration testing pads 38 do not leak into the sample and contaminate it. Therefore these dyes are fixed on to a membrane, and the test is dipped for a maximum of a set period of time, typically 1 minute.

Figs. 3 and 4 show a second embodiment of testing apparatus according to the present invention. The testing apparatus is generally similar to that of Fig. 1. In this embodiment the adulteration panel 36, including five discrete pads 38, is provided on the back of the housing 14, whilst the openings 32 exposing the sample receiving portions 28 of the test strips 26 are on the front. In use the bottom of the dip card is dipped in the urine sample as previously described so that the pads 38 and the sample receiving portions 28 are immersed.

Fig. 5 illustrates a third embodiment of a testing apparatus according to the invention. In this case, the testing apparatus is in the form of a test card 12 which may be dipped into a urine sample or wiped across an article to be tested for the presence of drugs. For example, the test card 12 could be wiped across a subject's desk, computer, luggage, etc. The test card 12 is of similar construction to the dip card 10 of Fig. 1, including front and rear panels sandwiching a grid member therebetween. As in the Fig. 1 embodiment, test devices in the form of test strips 26 are housed within the grid member and thereby sandwiched between the front and rear panels. However, in the embodiment of Fig. 5, the test strips 26 protrude beyond an end 40 of the test

card 12. In addition, the front panel 16 has a base which stops short of a base of the rear panel 42. This allows the rear panel 42 to flex as the card is wiped over desk tops, suitcases, etc.

An alternative embodiment includes a reservoir of fluid which moistens the protruding pad so that when in contact with a surface the moist pad is more likely to attract traces of powder or deposit.

Adulteration test means in the form of three discrete adulteration test pads 38 are provided between the ends of the test strip 26.

In use, the test card is wiped over the object to be tested, so that the ends of the test strips 26 come into contact with any sweat, etc. left on the object. The test card 12 is then put into a cup of fluid containing various substances, for example solvents to dissolve cannabis resin, proteins, surfactants, etc. These substances enable any drugs within the sample to dissolve and be detected by the test strips 26. The fluid also comes in contact with the adulteration test pads 38, which test for any adulteration as discussed above.

Fig. 6 shows a fourth embodiment of testing apparatus according to the present invention. In this embodiment, there is only one drug being tested for, hence only one test strip 26 is provided. A well 44 is provided, in which the sample receiving portion 28 of the strip 26 is exposed. The adulteration test pads 38 are also located in the well 44, on the sample receiving portion 28 of the strip 26.

In use the sample is dropped by pipette into the well 44 onto the pads 38 and sample receiving portion 28. Results are read as before through a window 34 at the reaction portion 30 of the strip 26. This embodiment is advantageous in situations where it is difficult or impossible to obtain a significant quantity of the sample to be tested. For example in hospitals where a patient is suspected to be in a drug-induced coma, a small urine sample may be collected with a catheter and tested with this apparatus to determine what drug the

patient has taken.

Figs. 7A to 7C illustrate a further embodiment of the invention. In this embodiment a grid member 18 is sandwiched between front and rear panels, as described in relation to the Fig. 1 embodiment. However, the front panel 16 is cut short, enabling test strips 26 to be exposed at their ends. An adulteration test pad 38 is affixed to an end of the rear panel.

The testing devices described above are designed for testing for multiple or single drugs in a sample of urine or sweat but the design is applicable to the testing of other samples. Therefore, this application is not limited to drug testing but may be applied to a wide range of test or screening methods, for example for protein and sugars in urine, protein and antibodies in milk, harmful bacteria in beer or other liquids, where adulteration, excess dilution etc. may affect the test results.

Although the apparatus tests fluid media, it can be used to detect substances present on objects for example in solid form. In this case, the apparatus is wiped over the object to pick up the substance and is subsequently dipped in a fluid in order to dissolve or suspend the substance to be tested for.

Various modifications may be made without departing from the spirit or scope of the present invention. For example, only one pad may be provided to test for only one form of adulteration. Testing apparatus without a housing may be used, for example a test strip with adulteration test pads on its sample receiving portion (see Fig. 8). The pads could be provided downstream of the sample receiving portion on the test strips, for example at the reaction area.

Whilst endeavouring in the foregoing specification to draw attention to those features of the invention believed to be of particular importance it should be understood that the Applicant claims protection in respect of any patentable feature or combination of features hereinbefore referred to and/or shown in the drawings whether or not particular emphasis has been placed thereon.

Claims

1. Testing apparatus for testing a fluid medium, the apparatus including a test device for providing an indication as to the presence of a selected substance within the medium and adulteration testing means for testing for adulteration of the sample which may affect the indication provided by the test device.

2. Testing apparatus according to claim 1, wherein the testing apparatus includes a single article incorporating the test device and the adulteration testing means.

3. Testing apparatus according to claim 1 or claim 2, wherein the test device includes a lateral flow membrane.

4. Testing apparatus according to any of the preceding claims, wherein the test device is in the form of a test strip.

5. Testing apparatus according to any of the preceding claims, wherein the test device includes a sample receiving portion provided at or towards an end of the test device.

6. Testing apparatus according to claim 5, wherein the test device further includes a reaction portion which provides the indication as to the presence of the selected substance within the medium.

7. Testing apparatus according to claim 6 when dependent on claim 5, wherein the reaction portion is spaced from the sample receiving portion.

8. Testing apparatus according to any of claims 5 to 7, wherein the adulteration testing means is provided at or near the sample receiving portion of the test device.

9. Testing apparatus according to any of the preceding claims, wherein the testing apparatus includes a housing the test device is mounted on or within the housing.

10. Testing apparatus according to claim 9 when dependent on claim 5, wherein the housing is provided with an opening adjacent to the sample receiving portion of the test device.

11. Testing apparatus according to claim 10, wherein the housing further includes an opening adjacent to a reaction portion of the test device.

12. Testing apparatus according to any of claims 9 to 11, wherein the housing includes two generally planar panel members between which the test device is sandwiched.

13. Testing apparatus according to any of claims 9 to 12, wherein the testing apparatus includes a plurality of test devices, each including a lateral flow membrane.

14. Testing apparatus according to claim 13, wherein each test device includes a sample receiving portion, the respective sample receiving portions being aligned towards an end of the housing.

15. Testing apparatus according to claim 14, wherein the adulteration testing means is mounted on or within the housing near to the sample receiving portions of the test device.

16. Testing apparatus according to claim 15, wherein the housing includes a plurality of discrete openings adjacent to the respective sample receiving portions of the test device.

17. Testing apparatus according to claim 16, wherein the housing further includes a plurality of discrete openings adjacent to the reaction portions of the test devices.

18. Testing apparatus according to any of the preceding claims, wherein the adulteration testing means includes means for testing for a plurality of different modes of adulteration.

19. Testing apparatus according to any of the preceding claims, wherein the adulteration testing means includes a pad of material impregnated with a chemical reagent.

20. Testing apparatus according to claim 19, wherein the adulteration testing means includes a plurality of pads of material impregnated with respectively different chemical reagents.

21. Testing apparatus according to claim 20, wherein the adulteration test means includes a plastics strip member on which the plurality of pads of material are mounted.

22. Testing apparatus according to any of the preceding claims, wherein the fluid medium to be tested is a urine sample and the selected substance is a drug.

23. Testing apparatus according to any of the preceding claims, wherein the adulteration testing means includes means for testing for dilution of the fluid medium.

24. Testing apparatus according to any of the preceding claims, wherein the adulteration testing means includes means for testing the specific gravity of the fluid medium.

25. Testing apparatus according to any of the preceding claims, wherein the adulteration testing means includes means for testing the levels or creatanine within the fluid medium.

26. Testing apparatus according to any of the preceding claims, wherein the adulteration testing means includes means for testing the pH of the fluid medium.

27. Testing apparatus according to any of the preceding claims, wherein the adulteration means includes means for testing for the presence of glutaraldehyde within the fluid medium.

28. Testing apparatus according to any of the preceding claims, wherein the adulteration testing means includes means for testing for the presence of pyridinium chlorochromate within the fluid medium.

29. Testing apparatus according to any of the preceding claims, wherein the adulteration testing means includes means for testing for the presence of nitrates within the fluid medium.

30. Testing apparatus substantially as hereinbefore described with reference to Figs. 1 and 2 of the drawings.

31. Testing apparatus substantially as hereinbefore described with reference to Figs. 3 and 4 of the drawings.

32. Testing apparatus substantially as hereinbefore described with reference to Fig. 5 of the drawings.

33. Testing apparatus substantially as hereinbefore described with reference to Fig. 6 of the drawings.

34. Any novel subject matter or combination including novel subject matter disclosed herein, whether or not within the scope of or relating to the same invention as any of the preceding claims.

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Application No: GB 0115763.5
Claims searched: All

Examiner: Michael R. Wendt
Date of search: 20 August 2001

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.S): G1B (BAA, BBS, BCB)

Int Cl (Ed.7): G01N 33/543, 33/94

Other: Online: EPODOC, WPI, Japio

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X – Y	EP 0860701 A1	("THE ULTIMAT" P.) - see Abstract.	1, 2, 4, 18, 22, 23 at least - 3, 12, 13 at least
Y	WO 00/63697 A1	(BIO MEDICA) e.g. see Abstract; page 20 lines 6 etc; page 12 lines 19 etc;	3, 12, 13 at least
Y	WO 00/62060 A2	(CHIMERA R & C.) e.g. see Claims 11 - 13; Page 1 lines 9 - 14; pages 8 - 14; Examples.	3, 13 at least
X - Y	US 5916815	(N. M. REVIEW) e.g. see Figure 1 at "36" & Figure 2; Claims 1 & 2; Column 5 lines 20 etc.	1, 2, 4 - 6, 8, 19, 22 at least - 3, 12 ,13 at least

X Document indicating lack of novelty or inventive step
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